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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/694,130

10/27/2003

William Michael Glandorf

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06/06/2005

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EXAMINER

KRASS, FREDERICK F

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/694,130

Applicant(s)

GLANDORF ET AL.

Examiner

Frederick F. Krass

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 4-19-05 (RCE Request).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **Previous Rejections**

All previous rejections are withdrawn.

### **New Matter Rejection**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not support the specific negative exclusion of synthetic linear polymeric polycarboxylate salts from the instant claims (see specifically claims 1 and 10). Indeed, the specification does not even mention those specific polymers; the closest it appears to come is "synthetic anionic polymers (including polyacrylates and copolymer of maleic anhydride or acid and methyl vinyl ether)" at the last paragraph of col. 7. A patent disclosure cannot specifically exclude what it never specifically discloses.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gaffar et al (USP 5,094,844) in view of Crisanti et al (USP 4,902,497).

The primary reference discloses anticalculus dentrifice compositions comprising linear polyphosphates having an average chain length of up to 125 repeating units, with hexametaphosphates (i.e., compounds having six repeating units) being preferred, in amounts ranging from 0.1 to 7.0 percent by weight. See col. 2, lines 49-66. It does not contain a synthetic linear polymeric polycarboxylate salt, instead containing a polymeric vinyl phosphate as a hydrolysis inhibitor. (See col. 2, lines 19-36, for example). When the dentrifice is a toothpaste, it may contain as low as 3 percent water by weight (col. 5, line 56); in lozenge or chewing gum form, it may contain no, or almost no water. (See working examples 5

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and 6 at col. 9.) Note that the disclosure of such low amounts of water reads on the same low amounts of water in the instant claims, whether the reason for using it is the same or different from Applicant's (the latter being "to inhibit hydrolysis" of the polyphosphate). A fluoride ion source, such as those recited by instant claim 11 (see the passage bridging col. 3, line 53 to col. 4, line 5), and thickening agents, such as those recited by instant claim 12 (see the passage spanning col. 5, line 59 to col. 6., line 13), are included as well. The primary reference differs from the instant claims insofar as it does not disclose stannous ion sources other than stannous fluoride or stannous monofluorophosphate, in an amount of 0.2:1 to 5:1 stannous ion to polyphosphate anion, which do not reduce the efficacy of the stannous ions in the dentrifice. It does, however, clearly teach at the first line of col. 7 that "other anticalculus agents" may be incorporated.

The secondary reference discloses the use of stannous compounds such as stannous chloride and stannous glyconate, complexed with certain acids or alcohols, as anticalculus agents. See the passage spanning col. 1, line 64 to 3, line 25. Stannous chloride dihydrate, the preferred species of instant claim 6, may also be used. (See working example IV at the bottom of col. 5). Note that the ppm values given for stannous ions at the top of col. 3 are for a toothpaste which has been diluted with water by a factor of three. (Col. 3, lines 3 and 4). This means that the dentrifice composition contained three times those values prior to dilution, i.e. at least 3000ppm stannous ions, as required by instant claim 3. The advantage of using such complexed stannous compounds appears to reside in their improved and sustained bioavailability: see col. 2, lines 31-36. The secondary reference differs from the instant claims insofar as it is silent regarding the use of polyphosphates having an average chain length of at least four.

It would have been obvious to have used a stannous compound, such as stannous chloride dihydrate, as an additional anticalculus agent as suggested by the primary reference, motivated by the desire to provide improved and sustained bioavailability as taught by the secondary reference. The compositions resulting from this combination of references would thus contain from 0.1 to 7 percent by weight polyphosphate having an average chain length of at least 4, and at least 3000ppm stannous ions. Since these substantially overlap the percentages preferred by Applicant (see page 5, lines 26-30 of the specification; see also instant claim 3), these compositions would necessarily contain the same relative

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proportions of polyphosphate anion to stannous ion recited instantly. And, insofar as can be determined, the efficacy of the dentrifice would not be reduced (to the contrary, it would be expected to be increased due to improved bioavailability).

Regarding instant claim 9, the selection of the value "21" from the range disclosed by the primary reference (up to 125) would have been obvious given that value's implicit inclusion within the disclosed range. See In re Peterson, 315 F.3d 1325 (C.A. Fed. 2003). (Stating that the "normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.")

#### **Obviousness-Type Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,696,045, taken in view of Gaffar et al (USP 5,094,844).

The conflicting claims recite dentrifies comprising 0.1 to 30 percent polyphosphate, an ion source which is stannous, fluoride or a mixture thereof, and a thickener which is a polysaccharide, carbomer, poloxamer or modified cellulose. Accordingly, the instant claims differ therefrom insofar as the latter do not specify the incorporation of those particular thickeners. It is well-known, however, to use polysaccharides, carbomers, poloxamers or modified celluloses as thickeners for dentrifies. See the

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secondary reference at the passage bridging col. 5, line 59 to col. 6, line 13, for example. Accordingly, it would have been obvious to have added a polysaccharide, carbomer, poloxamer or modified cellulose the dentrifices of the instant claims, motivated by the desire to impart the art-recognized thickening effect associated therewith as taught by the secondary reference.

2) Claims 1-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of USP 6,667,027.

The parent case was done by another examiner and is a paper file. That file is not in optimal condition, and it is difficult to determine if a restriction requirement was actually made. Applicant's aid is requested to clarify this situation; if a restriction requirement was issued, the examiner requests that a copy of the previous examiner's requirement be submitted with Applicant's response. If no restriction requirement was made, then the conflicting claims of the patent would be obvious on their face from the instant claims, since one would necessarily have to provide the single phase dentrifices of the instant claims to use them to reduce staining as recited by the conflicting claims.

The examiner thanks Applicants in advance for their cooperation in assisting the examiner in this matter.

### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 10:30AM- 7PM;  
Tuesday: 10:30AM - 7PM;  
Wednesday: off;  
Thursday: 10:30AM- 7PM; and  
Friday: 10:30AM-7PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

